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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L217595/142	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. CT/NZ2003/000140	International Filing Date (day/month/year) 3 July 2003	Priority Date (day/month/year) 3 July 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A01K 67/00, C07K 14/47, C12Q 1/68		
Applicant A2 CORPORATION LIMITED et al		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

5. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 28 January 2004	Date of completion of the report 25 October 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer TERRY MOORE Telephone No. (02) 6283 2632

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

II. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 13-15

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 13-15 (See also "observations")

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**Statement**

Novelty (N)	Claims 1-12 and 16	YES
	Claims	NO
Inventive step (IS)	Claims 1-12 and 16	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-12 and 16	YES
	Claims	NO

Citations and explanations (Rule 70.7)

The invention relates to methods for identifying cows that produce milk with a lower percentage of saturated fatty acids and a higher percentage of unsaturated fatty acids comprising identifying cows that produce β caseins with a proline at position 67.

Citations

WO 1996 036239

US 6 451 368

Laugeson et al (Jan 2003) The New Zealand Medical Journal 116(1168), 1-19

McLachlan (2001) Medical Hypotheses 56(2), 262-72

Bovenhuis H et al (1992) Science 75, 2549-559

Ojala et al (1997) J Dairy Science 80, 1776-85

Ikonen et al (1999) J Dairy Science 82, 1026-33

Novelty and Inventive Step

It is noted that claims 13-15 were not searched by the ISA and that no opinion is offered with respect to the novelty and inventive step of these claims.

None of the prior art teaches an association between specific β casein alleles in an animal and the ratio of saturated to unsaturated fatty acids in the milk of that animal.

Thus claims 1-12 and 16 are both novel and have an inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 13-16 lack support from the description. The specification describes the discovery that milk that contains proline 67 β casein has reduced saturated to unsaturated fatty acid ratios. Although this establishes a correlation between proline 67 β casein and milk with an altered fatty acid profile it does not establish proline 67 β casein as a causative agent of altered fatty acid profiles or provide support for methods where proline 67 β casein is used to alter fatty acid profiles. As such claims such as 13-16, which recite methods of altering saturated to unsaturated fatty acid ratios by adding β casein include within their scope methods that are not supported by the information in the specification.

Claims 13-15 are not supported by the description because the claims are not restricted to the use of bovine milk, which is the only source of proline 67 β casein disclosed in the specification.